UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

EISAI R&D MANAGEMENT CO., LTD. *et al.*,

Plaintiffs,

v.

SHILPA MEDICARE LIMITED, *et al.*,

Defendants.

No. 1:19-cv-19998

OPINION

APPEARANCES:

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On behalf of Defendants
Sun Pharmaceutical Industries Ltd.
and Sun Pharmaceutical Industries, Inc.

O'HEARN, District Judge.

This matter comes before the Court on the application for claim construction by Plaintiffs Eisai R&D Management Co., Ltd. ("ERDC"), Eisai Co., Ltd. ("ECL"), Eisai Manufacturing Ltd. ("EML"), Eisai Inc., ("ESI") (collectively, "Eisai"), MSD International GmbH[1] ("MSD") (collectively, "Plaintiffs"), and Defendants Sun Pharmaceutical Industries Ltd., Sun Pharmaceutical Industries, Inc. (collectively, "Sun"), and Shilpa Medicare Limited ("Shilpa") (collectively, "Defendants"). The parties seek construction of two claim terms in U.S. Patent No. 10,407,393 ("the '393 Patent"), which involves "lenvatinib mesylate," the active ingredient in Plaintiffs' cancer-treating drug product. The Court conducted *Markman* proceedings.[2] For the reasons that follow, the Court construes the two disputed terms within the '393 Patent as set forth herein.

I. BACKGROUND

On February 13, 2015, the United States Food and Drug Administration ("FDA") approved ESI's New Drug Application ("NDA") No. 206947. (Am. Compl., ECF No. 10, ¶ 16). ESI markets and sells oral capsules under the brand name LENVIMA® for the treatment of certain types of cancers. (ECF No. 10, ¶¶ 16–17). The LENVIMA® labeling states that "LENVIMA capsules for oral administration contain 4 mg or 10 mg of lenvatinib, equivalent to 4.90 mg or 12.25 mg of lenvatinib mesylate, respectively." (ECF No. 10, ¶ 16).

[1] MSD was substituted in for MSD Oncology Holdings Ltd. due to a transfer of rights and obligations previously held by MSD Oncology Holdings Ltd. (Am. Compl., ECF No. 10, ¶ 18).

[2] The *Markman* hearing was held before the Honorable Zahid N. Quraishi, U.S.D.J. Subsequently, the case was transferred to the Honorable Georgette Castner, U.S.D.J., before the case was ultimately transferred to this Court. This Court offered the parties the opportunity to conduct a *Markman* hearing anew, which they jointly declined. The parties also confirmed that Defendants' recent amendments to the invalidity contentions, (ECF No. 179), were immaterial to the issues raised in this claim construction.

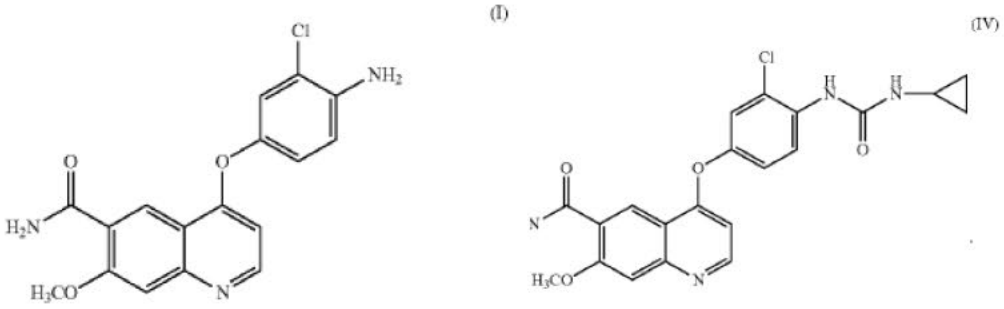
On September 10, 2019, the United States Patent and Trademark Office ("USPTO") issued the '393 patent, titled "High-Purity Quinoline Derivative and Method for Manufacturing Same" to ERDC,[3] which seeks to reduce the amount of impurities in lenvatinib mesylate, including a compound called "Impurity I"—referred to in the '393 Patent as "a compound represented by formula (I)" or "compound (I)." (ECF No. 10, ¶¶ 18, 20; Pla. Br., ECF No. 107-2, Ex. 1). Pursuant to the Hatch-Waxman Act, 21 U.S.C. § 355(b)(1), the '393 Patent is listed in the FDA's patent publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations* as covering LENVIMA®. (Am. Compl., ECF No. 10, ¶ 21).

Thereafter, Shilpa submitted Abbreviated New Drug Application ("ANDA") No. 213094, and Sun submitted ANDA No. 213092, to the FDA, seeking approval to manufacture, sell, and/or import generic lenvatinib mesylate oral capsules, EQ 4 mg base and EQ 10 mg base, prior to the expiration of the '393 Patent. (ECF No. 10, ¶ 22; 19-21857 Compl., ECF No. 1, ¶ 37). On November 11, 2019, Sun sent a letter providing notice to ERDC and ESI that it was seeking approval of ANDA No. 213092 prior to the expiration of the '393 Patent. (19-21857 Compl., ECF No. 1, ¶ 38). On December 19, 2019, Shilpa sent a letter providing notice to ERDC and ESI that it was seeking approval of ANDA No. 213094 prior to the expiration of the '393 Patent. (Am. Compl., ECF No. 10, ¶ 24).

The '393 Patent lists three claims, two of which contain terms disputed by the parties:

> 1. The methanesulfonate salt of a compound represented by formula (IV), wherein the content of a compound represented by formula (I) is 183 ppm by mass or less.

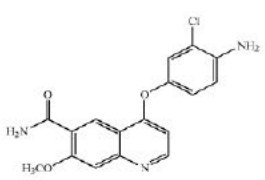
[3] ERDC is the assignee of the '393 Patent, ECL an exclusive licensee of the '393 Patent, and EML and MSD are co-exclusive sub-licensees of the '393 Patent. (Am. Compl., ECF No. 10, ¶ 18).



2. The methanesulfonate salt of a compound represented by formula (IV) according to claim 1, wherein the content of the methanesulfonate salt of a compound represented by formula (IV) is 98.0% by mass or more.

3. The methanesulfonate salt of a compound represented by formula (IV) according to claim 1, wherein the content of the compound represented by formula (I) is determined by the HPLC.

(Pla. Br., ECF. 107-2, Ex. 1). Specifically, the parties ask the Court to construe two claim terms:

Claim Term	**Plaintiffs' Proposed Construction**	**Defendants' Proposed Construction**
Claim 1: "the content of a compound represented by formula (I) is 183 ppm by mass or less"	Plain and ordinary meaning, which is: "the content of a compound represented by  is 183 ppm by mass or less"	Plain and ordinary meaning (i.e. includes 0 ppm)
Claim 2: "wherein the content of the methanesulfonate salt of a compound represented by formula (IV) is 98.0% by mass or more"	"wherein the content of the methanesulfonate salt of the compound comprises 98.0% by mass or more of the methanesulfonate salt of the compound represented by formula (IV) and may further comprise a starting material or a byproduct that may be formed as impurities"	"wherein the composition, inclusive of water and any other constituents present therein, comprises at least 98.0% by mass lenvatinib methanesulfonate" or indefinite

II. PROCEDURAL HISTORY

On November 8, 2019, Plaintiffs filed a Complaint in Case No. 19-19998 against Shilpa asserting an alleged infringement of U.S. Patent No. 10,259,791 ("the '791 Patent"). (ECF No. 1). On December 23, 2019, Plaintiffs filed a Complaint against Sun in Case No. 19-21857, asserting an alleged infringement of both the '791 and '393 Patents. (19-21857 Compl., ECF No. 1). Plaintiffs filed an Amended Complaint in Case No. 19-19998 on February 3, 2020, adding Shilpa's alleged infringement of the '393 Patent. (ECF No. 10). On March 23, 2020, Case No. 19-21857 and Case No. 19-19998 were consolidated for pre-trial purposes. (ECF No. 23). Plaintiffs filed a third action against Shilpa alleging infringement of U.S. Patent No. 9,006,256 ("the '256 Patent") on June 1, 2020. (20-6729 Compl., ECF No. 1). This case was consolidated with Case No. 19-19998 on July 23, 2020. (ECF No. 52). On October 30, 2020, all claims, counterclaims, and defenses related to the '791 Patent were dismissed without prejudice. (ECF No. 63). On June 25, 2021, the case regarding the '256 Patent was stayed. (ECF No. 96). The '393 Patent is the only active patent-in-suit implicated in these *Markman* proceedings.

On April 9, 2021, the parties submitted their Joint Claim Construction and Prehearing Statement pursuant to Local Patent Rule 4.3. (ECF No. 86). The parties submitted an Amended Joint Claim Construction and Prehearing Statement ("AJCCPS") on July 23, 2021, adding a second claim term. (ECF No. 99). The parties filed their opening briefs on September 24, 2021 (ECF Nos. 106, 107), and their responsive briefing on November 23, 2021 (ECF Nos. 109, 110). A *Markman* hearing was held on February 9, 2022. (ECF No. 133).

In this consolidated action, Plaintiffs seek relief for Defendants' alleged infringement of the patents-in-suit based on the respective filings of Shilpa's ANDA No. 213094 and Sun's ANDA No. 213092. Defendants deny Plaintiffs' claims on grounds of invalidity and noninfringement.

III. LEGAL STANDARDS

A. Claim Construction

Claim construction—a question of law that the Court decides—is a threshold issue the Court must address before analyzing infringement and/or invalidity. *Merck Sharp & Dohme Corp. v. Teva Pharms. USA, Inc.*, No. 17-6921, 2019 WL 943532, at *1 (D.N.J. Feb. 26, 2019) (citing *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 391 (1996)). "It is a 'bedrock principle' of patent law that 'the claims of a patent define the invention to which the patentee is entitled the right to exclude.'" *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004)). Claim construction is the first step in a two-step process to assess patent infringement or validity. *See Wright Med. Tech, Inc. v. Osteonics Corp.*, 122 F.3d 1440, 1443 (Fed. Cir. 1997). The second step is the analysis of infringement. *Id.* "The Court decides claim construction as a matter of law: 'the construction of a patent, including terms of art within its claim, is exclusively within the province of the court.'" *Shire LLC v. Amneal Pharms., LLC*, No. 11-3781, 2013 WL 4045622, at *2 (D.N.J. Aug. 8, 2013) (quoting *Markman*, 517 U.S. at 372).

When construing a claim, "the words of a claim 'are generally given their ordinary and customary meaning.'" *Phillip*, 415 F.3d at 1312 (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). The ordinary and customary meaning of a claim term is "the meaning that the term would have to a person of ordinary skill in the art [("POSA")] in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Id.* at 1312–13. The POSA is "deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." *Id.* at 1313.

To be sure, "the analytical focus must begin and remain centered on the language of the claims themselves, for it is that language that the patentee chose to use to 'particularly point out and distinctly claim the subject matter which the patentee regards his invention.'" *Interactive Gift Exp., Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1331 (Fed. Cir. 2001) (quoting 35 U.S.C. § 112). During claim construction, in addition to the patent specification, courts "should also consider the patent's prosecution history, if it is in evidence." *Phillips*, 415 F.3d at 1317 (citation omitted). The Court may also consider extrinsic evidence, like expert testimony and treatises, if it is "helpful in determining the true meaning of language used in the patent claims." *Id.* at 1318 (internal quotation marks and citation omitted). Yet, extrinsic evidence has been deemed "less significant than the intrinsic record in determining 'the legally operative meaning of claim language.'" *Id.* at 1317–18 (quoting *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 862 (Fed. Cir. 2004)).

B. Indefiniteness

"[A] patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014). To demonstrate indefiniteness, the alleged infringing party must show that the POSA would not be able to discern the scope of the claim by clear and convincing evidence. *Id.* at 908–09. "[T]he definiteness requirement must take into account the inherent limitations of language" and a "modicum of uncertainty" is permitted due to those limitations. *Id.* at 909 (citations omitted).

IV. DISCUSSION

A. POSA

As an initial matter, "before reviewing the claims, the Court 'must establish the level of skill that a POSA possessed at the time of the invention'" even if it does not affect the construction of the disputed terms. *Merck Sharp*, 2019 WL 943532, at *3 (quoting *Supernus Pharm., Inc. v. Actavis. Inc.*, No. 14-7272, 2016 WL 901837, at *2 (D.N.J. Mar. 9, 2016)). In determining the level of skill required of the POSA, courts may consider the following factors:

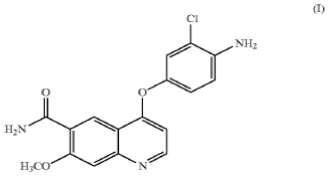
> (1) the educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) educational level of active workers in the field.

Env't. Designs, Ltd. v. Union Oil Co., 713 F.2d 693, 696–97 (Fed. Cir. 1983) (citation omitted). As the parties did not provide sufficient information to evaluate all the factors, *see Merck Sharp*, 2019 WL 943532, at *4, and given the fact that the parties agree that the definition will not affect the outcome of the claim construction, the Court adopts the parties' agreed-upon definition: that the POSA would have had a Master's or doctoral degree in organic chemistry, or related field, and at least three to five years of relevant experience. (*Markman* Tr., ECF No. 133 at 17:11–25).

B. Claim 1: "The methanesulfonate salt of a compound represented by formula (IV), wherein the content of a compound represented by formula (I) is 183 ppm by mass or less"[4]

The first term in dispute—"the content of a compound represented by formula (I) is 183 ppm by mass or less"—is Claim 1 of the '393 Patent:

[4] In their AJCCPS, the parties advised the Court that they agreed that the term "a methanesulfonate salt of a compound represented by formula (IV)" in Claim 1 means "a methanesulfonate salt of a compound that comprises 90% by mass or more of the methanesulfonate salt of the compound represented by formula (IV) and may further comprise a starting material or a byproduct that may be formed as impurities." (ECF No. 99 at 1–2).

Claim Term	**Plaintiffs' Proposed Construction**	**Defendants' Proposed Construction**
Claim 1: "the content of a compound represented by formula (I) is 183 ppm by mass or less"	Plain and ordinary meaning, which is: "the content of a compound represented by  is 183 ppm by mass or less"	Plain and ordinary meaning (i.e. included 0 ppm)

i. Plaintiffs' Position

In their opening brief, Plaintiffs argue that the plain and ordinary meaning of this term would be clear to a POSA. (Pla. Br., ECF No. 107 at 12). As such, Plaintiffs contend that the language used in the term does not require further explanation or elaboration. (ECF No. 107 at 12). Plaintiffs further argue that their proposal is consistent with the specification and prosecution history of the '393 Patent. (ECF No. 107 at 13). Specifically, Plaintiffs note that the specification uses identical language, which they argue makes clear that the phrasing was intentional and supports that the term should be understood in accordance with the plain and ordinary meaning. (ECF No. 107 at 13). Regarding the prosecution history, Plaintiffs note that during prosecution, the examiner reviewed the term as written and did not raise any issues with the term, which Plaintiffs argue supports that the language of the term is clear and conveys its plain and ordinary meaning. (ECF No. 107 at 14). Plaintiffs also maintain that their construction is consistent with regulatory guidelines. (ECF No. 107 at 15).

Finally, Plaintiffs argue that Defendants' proposed construction—by adding an "i.e.,"—would transform this term from a phrase reciting an upper limit on the amount of Impurity I to a

term reciting a single value—"0 ppm"—that is "included." (ECF No. 107 at 16). Plaintiffs note that this "is not how the patentees wrote their claim, nor how it was examined by the patent office, and it should not be how the claim is rewritten in a litigation under the guise of *Markman* proceedings." (ECF No. 107 at 16). Additionally, Plaintiffs note that the phrase "0 ppm" was not used by the inventors in the intrinsic record at all. (ECF No. 107 at 16).

In their responsive brief, Plaintiffs contend that the application of claim language is best suited for the second step of an infringement analysis, not for *Markman* proceedings, reiterate that the language is clear on its face and should not be changed, and that the focus of Claim 1 is on the upper limit. (Pla. Resp., ECF No. 110 at 6, 8).

ii. Defendants' Position

Defendants request that this Court clarify the phrase "183 ppm by mass or less" to allow Claim 1 to cover the absence of compound (I) in the claimed methanesulfonate salt. (Def. Br., ECF No. 106 at 5). Defendants maintain that because "or less" does not specify a lower limit for the claimed range, the lower limit must be zero. (ECF No. 106 at 5). Defendants argue their proposed construction is supported by the claim language and surrounding language of Claim 1. (ECF No. 106 at 6). Indeed, Defendants argue that "the language '90% by mass or' required by Claim 1 and '98% by mass or more' required by Claim 2 allow for a salt that comprises 100% by mass of the methanesulfonate of compound (IV)." (ECF No. 106 at 8). As such, Defendants maintain the claims themselves must be read to cover methanesulfonate salt that does not contain any starting materials or byproducts that may be formed as impurities, including compound (I). (ECF No. 106 at 8).

Defendants also maintain that their proposed construction is consistent with the patent specification. (ECF No. 106 at 8). Defendants further argue that if the term is construed not to

include "0 ppm," then there must be some defined lower limit. (ECF No. 106 at 10). Yet, because there would be no reasonable certainty as to what that lower limit would be, Claim 1 would be indefinite. (ECF No. 106 at 10).

In their responsive brief, Defendants argue that Plaintiffs, in opposing Defendants' construction, are implicitly asking this Court to require a positive, non-zero amount of Impurity I. (Def. Resp., ECF No. 109 at 2). Defendants maintain that their construction, "though asking this Court to provide some additional clarification," comports with the meaning of the words and is consistent with the intrinsic record. (ECF No. 109 at 3). Defendants further maintain that the '393 Patent specification "does not limit the claimed invention based on any particularly preferred 'acceptance criterion,' but instead makes clear that Impurity I may (or may not) be present in the claimed lenvatinib mesylate product." (ECF No. 109 at 5–6). Defendants also argue that Plaintiffs' citations to the prosecution history are irrelevant and that the Court should not consider any extrinsic evidence when the intrinsic evidence is sufficient to resolve any alleged ambiguity. (ECF No. 109 at 6–7). Finally, Defendants explain that they are simply asking this Court to confirm the indisputable: zero ppm is a value less than 183 ppm. (ECF No. 109 at 8).

iii. Analysis

In this case, the disputed term in Claim 1—"the content of a compound represented by formula (I) is 183 ppm by mass or less"—in the context of the '393 Patent can be understood by a POSA in accordance with its plain and ordinary meaning without the need for further explanation or clarification. Claim 1 states a specific upper limit of Impurity I. No further explanation is needed for a POSA to understand and apply this language. As the Federal Circuit has explicitly stated, claim terms with plain meanings "do not require additional construction." *ActiveVideo Networks, Inc. v. Verizon Communs., Inc.,* 694 F.3d 1312, 1326 (Fed.Cir.2012).

Indeed, the Court in *Nippon Steel & Sumitomo Metal Corp. v. POSCO*, concluded as much in evaluating similar upper limit terms like "0.015% or less of S" and 0.085% or less of C." No. 12-2429, 2014 WL 2534929, at *5–6 (D.N.J. June 4, 2014). There, the Court said these upper limit terms were "clear on their face," thus requiring no construction. *Id.* at 5. Like *Nippon Steel*, the disputed term here is clear as written. *See also Marine Polymer Techs. v. HemCon, Inc.*, No. 6-100, 2008 WL 1995454, at *7 (D.N.H. May 6, 2008), *rev'd on other grounds*, 659 F.3d 1084 (Fed. Cir. 2011), *aff'd on reh'g en banc*, 672 F.3d 1350 (Fed. Cir. 2012) (explaining the term "having a molecular weight of up to about 30 million daltons" "state[s] an upper limit on molecular weight but do[es] not include a lower limit. Given the stated molecular weights in the claims, a further definition is not necessary. In addition, the absence of a lower weight limit in the claims counsels against importing a limitation through claim construction from the specification."); *Takeda Pharm. Co. v. Zydus Pharms. USA, Inc.*, 743 F.3d 1359, 1365 (Fed. Cir. 2014) (concluding term "fine granules having an average particle diameter of 400 μm or less" meant "fine granules having an average particle diameter of precisely 400 μm or less").

Defendants' argument that "i.e., includes 0 ppm," must be read into the claim to cover methanesulfonate salts containing no starting material or byproduct impurities, (Def. Br., ECF No. 106 at 8), seeks to clarify a claim that needs no explanation by inserting language not used by the patentees. To be sure, "[t]he construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998). This is precisely why no further explanation is needed. As the Court noted in *Nippon Steel*, Defendants' proposed construction would "merely reword [the claim] in minor ways that provide no elucidation to matters which required none." 2014 WL 2534929, at *5.

That the claim is to be understood by the plain and ordinary meaning of the term is also consistent with the patent specification. In fact, the patent specification uses identical language as that of the claim: "[a] compound represented by formula (IV) or a salt thereof, wherein the content of a compound represented by formula (I) is 183 ppm by mass or less." (Pla. Br., ECF No. 107, Ex. 1 at 5:33–35). That the claim and patent specification use the same language suggests that the phrasing was intentional. Additionally, as the patent specification provides, the object of the invention is to provide highly pure lenvatinib mesylate with small amounts of impurities. (ECF No. 107, Ex.1 at 4:53–55). The patentees specifically set the upper limit of Impurity I as 183 ppm recognizing "it is difficult to constantly control the content of compound (I) in the compound (IV) . . . it is preferred that the content be in the As Low As Reasonably Practicable, i.e., be 183 ppm by mass or less. . . ." (ECF No. 107, Ex.1 at 24:65–25:4). The patent specification's use of the same language, thus, supports that the disputed term needs no explanation or modification.

Defendants unconvincingly point to the use of the phrase "may comprise" in the patent specification that defines "a compound or salt thereof" as "a compound or salt thereof that comprises 90% by mass or more of the compound and *may comprise* a starting material or a byproduct that may be formed as impurities," to justify its proposed inclusion of "i.e. includes 0 ppm" in the claim. (Def. Br., ECF No. 106 at 8) (emphasis added). Defendants argue that this definition makes clear that "the inventors intended to include within the scope of their invention a salt without any amount (i.e., 0 ppm) of Compound (I) as an impurity." (ECF No. 106 at 10). Yet, the use of "may comprise" merely explains that the lenvatinib mesylate substance may include impurities like Impurity I. The phrase does not suggest that a POSA would not understand that the term in Claim 1 sets an upper limit for Impurity I. Considering the language and purpose of the

patent, the term means exactly what it says. A POSA could understand and apply the language of the claim without the Court needlessly injecting "i.e., includes 0 ppm" into the claim.

Turning to the prosecution history, the Court agrees with Defendants that it is unclear from the prosecution history provided by Plaintiffs, (ECF No. 107-1, Ex. 10), that the examiner construed the disputed term one way or the other. Because the claim's language is clear on its face, however, the examiner's construction is immaterial here.

On the other hand, the regulatory guidelines, referred to as ICH Q6A, which the parties acknowledge were submitted at prosecution, (Pla. Br, ECF No. 107 at 15; Def. Resp., ECF No. 109 at 7), further support that a POSA would understand the term without additional clarification. The patent specification describes "≤183" ppm by mass of Impurity I as an "acceptance criterion." (Pla. Br., ECF No. 107, Ex.1, Table 2). And ICH Q6A defines "acceptance criteria" as "numerical limits, ranges, or other suitable measures for acceptance of the results of analytical procedures." (ECF No. 107, Ex. 11 at 18). Plaintiffs argue the definition of acceptance criteria in ICH Q6A is consistent with how a POSA would understand the plain meaning of the disputed term. (ECF No. 107 at 15). Plaintiffs maintain that by referring to "183 ppm or less" of Impurity I as "acceptance criteria" in the patent specification, the '393 Patent is setting forth an upper numerical limit on the acceptable amount of Impurity I. (ECF No. 107 at 15–16).

Defendants maintain that the ICH Q6A guideline definition of "acceptance criteria" "cannot possibly be read here as a basis to ignore the actual criterion report in the table—which confirms that the compound may exist without the enumerated impurity—since 'less than' does include zero." (Def. Resp., ECF No. 109 at 8).

The Court agrees with Plaintiffs. This evidence further supports that a POSA would understand the disputed term to set forth an upper limit. In fact, even Defendants' own expert agreed that the claim was clear. (Pla. Resp., ECF No. 110, Ex. 30 at 49:22–50:4).

Thus, for the reasons set forth above, the Court concludes that a POSA would readily understand the plain and ordinary meaning of the disputed term in Claim 1: "wherein the content of a compound represented by formula (I) is 183 ppm by mass or less."

Turning finally to indefiniteness, the Court declines to address the issue at this stage given "(1) the high burden of proof required to show indefiniteness and (2) its potentially dispositive, patent-invalidating nature." *Int'l Dev. LLC v. Richmond*, No. 09-2495, 2010 WL 4703779, at *17–18 (D.N.J. Nov. 12, 2010). As such, the Court defers the issue of indefiniteness to a more appropriate time. *See Merck Sharp*, 2019 WL 943532, at *6 (collecting cases); *see also Adapt Pharma Operations Ltd. V. Teva Pharms. USA, Inc.*, No. 16-7721, 2019 WL 1789463, at *4 (D.N.J. Apr. 24, 2019) ("It is not uncommon for courts to defer ruling on an indefiniteness challenge at the claims construction stage where such a ruling would be better suited for trial."); *Horizon Pharma, Inc. v. Dr. Reddy's Lab'ys, Inc.*, No. 15-3324, 2017 WL 5451748, at *5 (D.N.J. Nov. 14, 2017) ("This Court considers indefiniteness arguments on summary judgment or at trial, and not at claim construction."); *Alcon Research Ltd. V. Barr Labs., Inc.,* No. 09–0318, 2011 WL 3901878, at *16 (D. Del. Sept. 6, 2011) ("We find that the indefiniteness issue is best decided at trial and defer consideration on it until that time."); *Pharmastem Therapeutics, Inc.*, No. 02-148, 2003 WL 124149, at *2 n.1 (D. Del. Jan. 13, 2003) ("While the court recognizes that a determination of indefiniteness is necessarily intertwined to some degree with claim construction, it is clear that the court must first attempt to determine what a claim means before it can determine whether the claim is invalid for indefiniteness.").

C. Claim 2: "Wherein the content of the methanesulfonate salt of a compound represented by formula (IV) is 98.0% by mass or more"

The second term in dispute—"wherein the content of the methanesulfonate salt of a compound represented by formula (IV) is 98.0% by mass or more"—is Claim 2 of the '393 Patent:

Claim Term	Plaintiffs' Proposed Construction	Defendants' Proposed Construction
Claim 2: "wherein the content of the methanesulfonate salt of a compound represented by formula (IV) is 98.0% by mass or more"	"wherein the content of the methanesulfonate salt of the compound comprises 98.0% by mass or more of the methanesulfonate salt of the compound represented by formula (IV) and may further comprise a starting material or a byproduct that may be formed as impurities"	"wherein the composition, inclusive of water and any other constituents present therein, comprises at least 98.0% by mass levatinib methanesulfonate" or indefinite

i. Plaintiffs' Position

Plaintiffs maintain that their proposed construction is nearly identical to a construction for a similar term in Claim 1—"a methanesulfonate salt of a compound represented by formula (IV)"—that the parties had previously agreed on. (AJCCPS, ECF No. 99). Plaintiffs note that this agreed-upon construction on a similar term and their proposed construction on this term derives from a definition provided in the patent specification. (Pla. Br., ECF No. 107 at 19). Because their proposed construction closely follows the language of definitions in the patent specification, this would inform a POSA's understanding of the purity of the lenvatinib mesylate. (ECF No. 107 at 21).

Plaintiffs argue that Defendants' proposed construction violates the principles of claim construction as it finds no support in the claim or patent specification and is contrary to how a POSA would understand the specification and conduct relevant testing. (ECF No. 107 at 22). Indeed, Plaintiffs note it is unclear what Defendants mean by "the composition" in their proposed

construction for "compound." (ECF No. 107 at 22). Plaintiffs explain pharmaceutical compositions and compounds are not the same thing and Claims 1 and 2 only refer to a "a compound" not a "composition." (ECF No. 107 at 22). Additionally, Plaintiffs take issue with Defendants' use of the words "inclusive of water" as this phrase appears nowhere in the '393 Patent. (ECF No. 107 at 23). Plaintiffs note that the '393 Patent does not specify or suggest that water would be considered an impurity. (ECF No. 107 at 23).

Plaintiffs also assert that Defendants' construction is contrary to regulatory filings and that Defendants have admitted their construction is a belated about-face to create a noninfringement argument. (ECF No. 107 at 26). Finally, Plaintiffs argue that Defendants not only failed to prove indefiniteness, but this argument should not be decided in a *Markman* proceeding before the record has been developed. (ECF No. 107 at 28).

In their responsive brief, Plaintiffs echo these arguments and raise issues with Defendants' expert who, they note, effectively admitted at his deposition that Plaintiffs' construction of the disputed term in Claim 2 is consistent with the agreed-upon construction of the same term in Claim 1. (Pla. Resp., ECF No. 110, at 11). Plaintiffs further maintain that Defendants' expert conceded facts at deposition which suggest that his declaration was misleading and unreliable. (ECF No. 110 at 21).

ii. Defendants' Position

Defendants argue that the '393 Patent describes only one method to calculate the "percent by mass" of a compound in a composition and that this disclosed method accounts for the presence of water and any other constituents in the composition. (Def. Br., ECF No. 106 at 10–11). Defendants maintain that if the claim is not limited to this method, it would be invalid for indefiniteness because a different method to calculate the "percent by mass" would yield a different

result. (ECF No. 106 at 11). As such, Defendants argue, the bounds of this claim element could not be determined by a POSA with any reasonable certainty. (ECF No. 106 at 11).

More specifically, Defendants explain that the patent specification discloses three "purity tests" that are used to measure the amounts of different substances in samples created using the disclosed synthetic methods. (ECF No. 106 at 11). Defendants note that only "Purity Test 1" describes a method for determining the amount of compound (IV) in the final composition. (ECF No. 106 at 11). Defendants then detail the test, which includes using an ultraviolet (UV) light detector to determine where each substance, including both UV-active and UV-inactive substances (i.e., water), contained within the drug composition begin and end. (ECF No. 106 at 12–15). As Defendants maintain that "Purity Test 1," as they outlined, is the only method identified in the '393 Patent for determining percent by mass of lenvatinib, the claim should be construed consistent with the outcome of the method—which includes water and other constituents as part of the denominator. (ECF No. 106 at 10–16). Additionally, Defendants argue that if the claimed 98% does not account for water content, Claim 2 is indefinite. (ECF No. 106 at 16).

In their responsive brief, Defendants underscore these arguments and continue to maintain that their construction adopts the only method for determining "percent by mass" in the '393 Patent. (Def. Resp., ECF No. 109 at 11). Defendants argue that Plaintiffs' construction is ambiguous as it does not state how "percent by mass" should be determined despite Plaintiffs' expert opining that "percent by mass" as used in Claim 2 requires assessment of the amount of lenvatinib mesylate on an anhydrous basis. (ECF No. 109 at 11–12). Defendants note that the word "anhydrous" appears nowhere in the patent specification and is contrary to the specification itself. (ECF No. 109 at 12). Moreover, Defendants argue that Plaintiffs' expert opinion is inconsistent with the intrinsic and extrinsic evidence. (ECF No. 109 at 14–17).

Defendants also take issue with Plaintiffs' position that the parties' agreed-upon construction for the claim term "methanesulfonate salt of a compound represented by formula (IV)" supports their proposed construction as it does not define the term "percent by mass." (ECF No. 109 at 17–18). Defendants argue that their construction is not inconsistent with the regulatory filings since Defendants are not suggesting that there are different test methods that can be used to measure mass percent but that the '393 Patent only describes one way. (ECF No. 109 at 19). Defendants argue that if the patent applicants intended their patent claims to require testing on an anhydrous basis, they would have said so. (ECF No. 109 at 19).

Finally, Defendants continue to argue that there is no reason to delay resolution of the parties' dispute over this claim term, including to the extent that the claim is indefinite. (ECF No. 109 at 22).

iii. Analysis

Just as with Claim 1 of the '393 Patent, the Court finds that the plain and ordinary meaning of Claim 2—"wherein the content of the methanesulfonate salt of a compound represented by formula (IV) is 98.0% by mass or more"—would be clear to a POSA. The Court only adds the language proffered by Plaintiffs to maintain consistency with the language of Claim 1. Moreover, the proffered language is taken directly from the patent specification. For this claim construction, the Court focuses its analysis on the claim language itself and the patent specification since neither party relied on the prosecution history for Claim 2.

Claim 2 focuses on the invention of a high purity lenvatinib mesylate. (Pla. Br., ECF No. 107, Ex.1 at 4:53–56). Importantly, Claim 2 is dependent on Claim 1. *See* 37 C.F.R. § 1.75(c) ("One or more claims may be presented in dependent form, referring back to and further limiting another claim or claims in the same application."). Claim 1 includes the language "a

methanesulfonate salt of a compound represented by formula (IV)," which the parties agreed meant: "a methanesulfonate salt of a compound that comprises 90% by mass or more of the methanesulfonate salt of the compound represented by formula (IV) and may further comprise a starting material or byproduct that may be formed as impurities." (AJCCPS, ECF No. 99 at 1–2).

This agreed-upon language—which Plaintiffs now proposes for Claim 2—explicitly borrows from the inventor's definition in the patent specification of "a compound or salt thereof." The specification defines "a compound or a salt thereof" by setting forth a minimum amount of the drug substance itself that may be present in terms of a specified percent by mass. (Pla. Br., ECF No. 107, Ex.1 at 16:51–55). The specification provides:

> In the present specification, "a compound or salt thereof" refers to a compound or a salt thereof that comprises 90% by mass or more of the compound and may comprise a starting material or a byproduct that may be formed as impurities.

(ECF No. 107, Ex.1 at 16:51–55). The specification also states that "a compound represented by formula (IV) or a salt thereof," would fall within the definition of "a compound or salt thereof":

> For example, "a compound represented by formula (IV) or a salt thereof" comprises 90% by mass or more of the compound (IV) or a salt thereof and may comprises a starting material such as compound (I), a compound (A-I), and a byproduct such as compound (C-I) that may be formed in each production step.

(ECF No. 107, Ex.1 at 16:55–60).

As Claim 2 is dependent on Claim 1, and the parties have already agreed to what this precise language in Claim 1 means, the Court construes Claim 1 to mean precisely as it says, with the addition of the phrase Plaintiffs propose that is directly taken from the patent specification: "wherein the content of the methanesulfonate salt of the compound comprises 98.0% by mass or more of the methanesulfonate salt of the compound represented by formula (IV) and may further comprise a starting material or a byproduct that may be formed as impurities." *See In re Varma*, 816 F.3d 1352, 1363 (Fed. Cir. 2016) ("[T]he principle that the same phrase in different claims of

the same patent should have the same meaning is a strong one[.]"). This not only keeps the language of the term consistent with that of the parallel language of Claim 1, but it is also what the patent specification instructs is the meaning of the term. As Plaintiffs note, the only difference between the definition in the patent specification and Claim 2 is the numerical purity measure (i.e., 90% in Claim 1 and the specification, and 98% in Claim 2).

Defendants' proposed construction,[5] which includes the addition of the phrase "inclusive of water and any other constituents therein," inserts terms not otherwise specified by the inventors. As noted, the definition of "a compound or salt thereof" already provides the guidance to a POSA on what is included when determining the purity of lenvatinib mesylate. The Court also disagrees with Defendants' argument that it must determine the in-depth analysis of the method by which a POSA would determine the percent by mass of lenvatinib mesylate. Like Claim 1, Claim 2 deals with minimal and maximal purity measures sought to "provide a highly pure quinoline derivative with a small amount of impurities."

Additionally, as Plaintiffs note, both parties state that a POSA reading the '393 Patent would measure the percent by mass purity of lenvatinib mesylate using a calculation called an "assay." (Pla. Br., ECF No. 107 at 21–22; Def. Br., ECF No. 106 at 12–15). As underscored by both parties' experts agreeing on the assay equation to calculate the percent by mass, a POSA would know how to measure the lenvatinib mesylate to determine its purity. (Pla. Resp., ECF No. 110, Ex. 30 at 179:7–181:22; Pla. Br., ECF No. 107 at 12 ¶¶ 37–38). "[B]ecause descriptions in patents are addressed to those skilled in the art to which the invention pertains, an applicant for a

[5] At the *Markman* hearing and in reply, Defendants stated that they were amenable to changing their proposed word "composition" back to "compound" as the crux of their construction does not depend on which term is used. (*Markman* Tr., ECF No. 133 at 91:5–8; Def. Resp., ECF No. 109 at 18 n.8).

patent need not expressly set forth in his specification subject matter which is commonly understood by persons skilled in the art." *Edwards Lifesciences AG v. Corevalve, Inc.*, 699 F.3d 1305, 1309 (Fed Cir. 2012). Thus, the Court construes the term in Claim 2 to mean: "wherein the content of the methanesulfonate salt of the compound comprises 98.0% by mass or more of the methanesulfonate salt of the compound represented by formula (IV) and may further comprise a starting material or a byproduct that may be formed as impurities."

Finally, for the same reasons stated in Claim 1's construction, the Court declines to address indefiniteness at this stage.

CONCLUSION

For the foregoing reasons, the Court construes the disputed terms in Claims 1 and 2 as discussed herein. An appropriate Order accompanies this Opinion.

CHRISTINE P. O'HEARN
United States District Judge